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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,094	05/22/2000	Miles A. Galin	A31632-A	2498
23506	7590	05/10/2005	EXAMINER	
GARDNER GROFF, P.C. 2018 POWERS FERRY ROAD SUITE 800 ATLANTA, GA 30339			CHATTOPADHYAY, URMI	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/576,094

Applicant(s)

GALIN, MILES A.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6-10 and 21-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6-10 and 21-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/21/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 2/14/05 has been entered. The changes to the claims have been approved by the examiner. Claim 11 has been canceled. Claims 1, 6-10 and 21-40 are currently pending and are being considered for further examination on the merits.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 8-10 and 21-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,828,558 as cited in applicant's IDS) in view of Schepel et al. (USPN 5,135,540 as cited in last office action).

Kelman discloses an intraocular lens with all the elements of claim 21, but is silent to the transition portion extending normal to the peripheral edge of the lens. See Figure 2 for an ocular implant (1) comprising an optic lens having an anterior surface, a posterior surface and a peripheral edge therebetween. See Figure 1 for at least one haptic (3, 4) affixed to the lens, wherein each haptic has a generally "S"-shaped configuration with a smooth transition portion extending to the peripheral edge of the lens (Figure 2), an intermediate beam extending from the transition portion, and a concavely curved outer portion extending from the intermediate beam to

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define a first attachment point at the juncture of the intermediate beam and outer portion, and a second attachment point at the distal end of the outer portion. Schepel et al. teaches an intraocular lens wherein some material of the haptics is removed from the broad point of attachment to the lens so that the smooth transition portion of the haptic extends normal to the peripheral edge of the lens in order to permit greater movability of the haptics for flexure over the lens body. See Figure 2. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Schepel et al. to modify the IOL of Kelman by reducing the broad point of attachment of each haptic to the lens so that the transition portion extends normal to the peripheral edge of the lens in order to provide the haptic with greater movability for flexure over the lens body. This will facilitate their implantation through a small incision in the eye. See column 3, lines 31-45. In addition, this removal of material will provide the transition portion with a smooth concave curvature with a radius of curvature of less than 0.4mm (claims 30 and 31), which is shown in Figure 2.

Claims 22 and 23, see column 5, line 15 for both anterior and posterior surfaces being convex.

Claim 24, see column 5, lines 15-20 and column 7, line 28 for the convex structure and PMMA material (higher refractive index than surrounding medium) of the lens and concave structure of gas "layer" (lower refractive index) providing a positive optical power.

Claim 25, see column 7, lines 1-7 for the lens being foldable.

Claim 26, see column 5, lines 55-56 for the transition portion of each haptic having a thickness of *about* 0.2mm, which is broadly interpreted to fall within the required reduced thickness range.

With respect to claim 27, see Figure 1 for the intermediate beam length being slightly shorter than the optic diameter. Because the optic diameter is at most about 6 mm (column 5, lines 44-45), the intermediate beam length will be *approximately* 5.25mm. The word *approximately* broadens the scope of the claim, and since the specification does not define the metes and bounds of “approximately 5.25mm”, Examiner is broadly interpreting it.

With respect to claims 28, 29 and 32, because the haptics meet all the structural limitations and configuration requirements with respect to the optic lens, the ocular implant will have a vault, saggita value and omega value within the required ranges.

Claim 33, see rejection to claims 21, 22 and 24 supra and column 4, lines 4 for an anterior chamber ocular implant. With respect to the limitation of “for placement in the anterior chamber of a phakic eye”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Because the IOL of Kelman and Schepel et al. is capable of performing the intended use, being used in the anterior chamber of a phakic eye, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 34 and 35, see rejections to claims 26 and 27, supra.

Claims 36, 37 and 40, see rejections to claims 28, 29 and 30, supra.

Claims 38 and 39, see rejections to claims 30 and 31, supra.

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Claim 1, see rejection to claims 33-35, *supra*. The two haptics (3, 4) provide a four-point attachment. Because the IOL of Kelman and Schepel et al. have all the required structural limitations of applicant's claimed invention, if it were to be placed in the anterior chamber of a phakic eye, which it is certainly capable of being, contact of the lens with other anatomic bodies would be avoided, as would contact of the haptics with the iris and corneal endothelium.

Claim 8, see column 7, lines 27-29 for lens being fabricated from PMMA.

Claims 9 and 10, see column 7, lines 36-48.

4. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman and Schepel et al., as applied to claim 1 above, and further in view of Li et al. (USPN 6,132,462 as cited in previous office action).

Kelman, as modified by Schepel et al., discloses an intraocular lens with all the limitations of claim 1, but is silent to the additional limitation of the implant being coated with a specific sulfated polysaccharide medicament, as required by claims 6 and 7. Li et al. teaches a copolymer intraocular lens coated with heparin in order to raise biocompatibility and prevent deposition of cells. See column 6, lines 19-29. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Li et al. to modify the intraocular lens of Kelman, as modified by Schepel et al., by including the specific coating in order to raise biocompatibility and prevent deposition of cells.

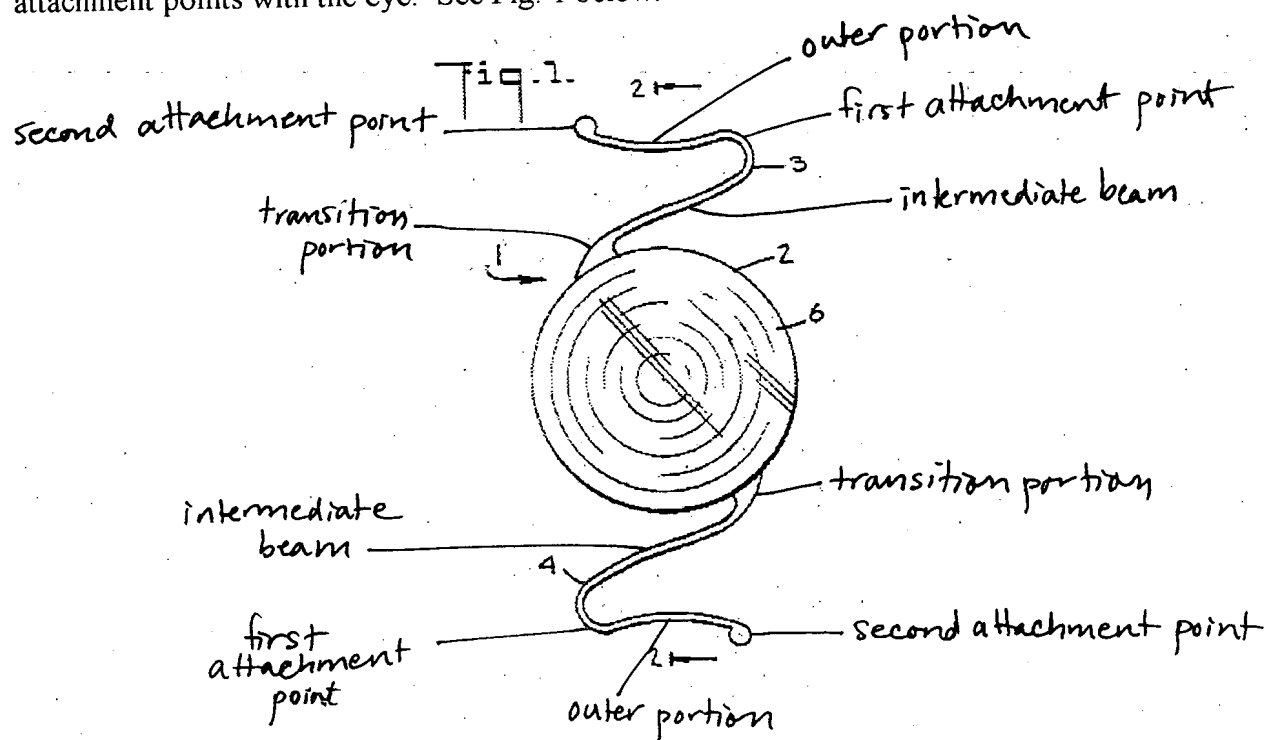
***Response to Arguments***

5. Applicant's arguments filed 2/14/05 have been fully considered but they are not persuasive. In response to applicant's argument that because Kelman and Schepel et al. disclose haptic geometrics that are quite distinct from one another, one skilled in the art would not be motivated to alter either in the manner proposed, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Schepel et al. is used only to teach making the transition portion extend normal to the peripheral edge of the lens. Both Kelman and Schepel disclose a broad point of attachment of each haptic to the lens. Schepel further teaches reducing the broad point of attachment so that the transition portion extends normal to the peripheral edge of the lens in order to provide the haptic with greater movability for flexure over the lens body. Therefore, it indeed would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Schepel et al. to reduce the broad point of attachment of Kelman so that the transition portion extends normal to the peripheral edge of the lens in order to provide the haptic with greater movability for flexure over the lens body. This will facilitate their implantation through a small incision in the eye. The motivation to combine references is provided by Schepel, and therefore, is not improper hindsight.

6. Applicant also argues that neither Kelman nor Schepel, alone or in combination, disclose, teach or suggest a first attachment point at the junction of the intermediate beam and the outer

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portion, and a second attachment point at a distal end of the outer portion, as recited in independent claims 21 and 33, or two haptics providing a four-point attachment, as recited in claim 1. The examiner disagrees. Absent any further structural and/or functional limitations to further define the first and second attachment points, Kelman does indeed disclose first and second attachment points as claimed, and two haptics providing a four-point attachment. When the IOL is inserted into the eye, the first and second attachment points of each haptic are the attachment points with the eye. See Fig. 1 below.



### Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire ~~THREE~~

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO



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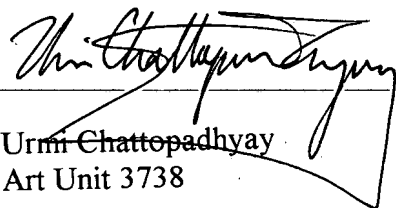
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

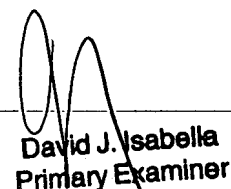
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay  
Art Unit 3738



David J. Isabella  
Primary Examiner